addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

Note 2: Paragraph (a) of this AD merely restates the requirements of paragraph (a) of AD 95–06–04, amendment 39–9174. As allowed by the phrase, ''unless accomplished previously,'' if those requirements of AD 95–06–04 have already been accomplished, this AD does not require that those actions be repeated.

To prevent failure of the horizontal stabilizer primary trim motor, accomplish the following:

(a) For airplanes listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994: Within 6 months after April 21, 1995 (the effective date of AD 95–06–04, amendment 39–9174), conduct a visual inspection of the horizontal stabilizer primary trim motor to determine if the motor is identified with one of the suspect serial numbers listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, dated August 4, 1994, or Revision 1, dated May 15, 1995. Conduct this inspection in accordance with the procedures specified in that service bulletin.

(1) If the horizontal stabilizer primary trim motor is not identified with a suspect serial number, no further action is required by this AD.

(2) If the horizontal stabilizer primary trim motor is identified with a suspect serial number, prior to further flight, accomplish either paragraph (a)(2)(i) or (a)(2)(ii) of this AD.

(i) Replace the motor in accordance with the McDonnell Douglas alert service bulletin. Or

(ii) Modify the motor in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; and install the modified motor in accordance with the McDonnell Douglas alert service bulletin.

(b) For airplanes listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, Revision 1, dated May 15, 1995, and not subject to paragraph (a) of this AD: Within 6 months after the effective date of this AD, conduct a visual inspection of the horizontal stabilizer primary trim motor to determine if the motor is identified with one of the suspect serial numbers listed in McDonnell Douglas MD–80 Alert Service Bulletin A27–342, Revision 1, dated May 15, 1995. Conduct this inspection in accordance with the procedures specified in that service bulletin.

(1) If the horizontal stabilizer primary trim motor is not identified with a suspect serial number, no further action is required by this AD.

(2) If the horizontal stabilizer primary trim motor is identified with a suspect serial number, prior to further flight, accomplish either paragraph (b)(2)(i) or (b)(2)(ii) of this AD.

(i) Replace the motor in accordance with the McDonnell Douglas alert service bulletin. Or

(ii) Modify the motor in accordance with Sundstrand Service Bulletin 9590–27–012, dated August 8, 1995; and install the modified motor in accordance with the McDonnell Douglas alert service bulletin.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on September 20, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–23809 Filed 9–25–95; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309 and 1310

[DEA–133P]

RIN 1117–AA29

Waiver of Requirements for the Distribution of Prescription Drug Products That Contain List I Chemicals

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: DEA is proposing to amend its regulations to waive the registration requirement for persons who distribute prescription drug products that are subject to regulation as List I chemicals and to allow that the records required to be maintained pursuant to the Federal Food and Drug Administration (FDA) guidelines for prescription drug products shall be deemed adequate for satisfying DEA's recordkeeping requirements with respect to distribution. In response to requests from industry, DEA has conducted a review and determined that such prescription drug products are already subject to extensive regulatory controls regarding their distribution and are not presently identified as a significant source for diversion of List I chemicals to the illicit manufacture of controlled substances. This proposed action will relieve a large population of distributors and manufacturers of regulated prescription drug products containing List I chemicals from the burden of compliance with regulations in circumstances where compliance would be unnecessary for enforcement of the law.

DATES: Comments or objections must be received on or before November 27, 1995.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: The Domestic Chemical Diversion Control Act of 1993 (PL 103–200) (DCDCA) amended Section 802(39) of the Controlled Substances act (21 U.S.C. 801 et seq.) (CSA) to remove drug products that contain either ephedrine as the sole medicinal ingredient or ephedrine in combination with therapeutically insignificant amounts of another medicinal ingredient (hereinafter regulated ephedrine drug products) from the exemption granted to drug products that contain a List I chemical that may be marketed or distributed under the Federal Food, Drug and Cosmetic Act (FDCA). As a result of this and the removal of the ephedrine threshold, all distributions, importations and exportations of regulated ephedrine drug products became subject to the chemical registration, recordkeeping and reporting requirements of the CSA. The intent of these actions was to establish a system of controls to prevent the diversion of regulated ephedrine drug products for the illicit manufacture of controlled substances.

DEA has received a number of comments from pharmaceutical companies expressing concerns regarding the application of the new controls to the distribution of prescription drug products that are subject to regulation. Primary among the concerns are: (1) The burdens associated with compliance with the registration and recordkeeping requirements, including the financial burden associated with converting existing systems to satisfy the new requirements; (2) existing Federal and state controls severely restrict the manufacture, distribution or dispensing of the

products, and; (3) the lack of any evidence that the products are being diverted for the illicit manufacture of controlled substances.

In response to industry's concerns and in the interest of limiting regulatory burdens to those necessary for the enforcement of the law, DEA has reviewed the need for applying the chemical registration requirement on persons who distribute regulated prescription drug products and determined that such application is not necessary for the enforcement of the CSA at this time. Further, DEA has determined that distribution records required to be maintained pursuant to the FDA guidelines set forth in title 21, Code of Federal Regulations (21 CFR), Part 205 are adequate for satisfying DEA's recordkeeping requirements for distributions. This determination is based on DEA's finding that there is presently a lack of evidence that prescription drug products that contain List I chemicals are being diverted for the illicit manufacture of controlled substances, the products are already subject to an extensive system of regulatory controls, and the DEA access to the distribution records kept under the FDA guidelines should provide sufficient information to satisfy the intent of the regulations.

With respect to diversion, it has been DEA's experience that persons seeking to divert List I chemicals for the illicit manufacture of controlled substances have relied primarily on either non-regulated sources or smuggled chemicals. Initially, bulk ephedrine was the chemical of choice; following implementation of DEA's chemical control program in 1989, over-the-counter (OTC) ephedrine drug products which were exempt from the regulatory provisions of the CSA became the products of choice. With implementation of the DCDCA and regulation of the OTC ephedrine drug products, OTC pseudoephedrine drug products became a significant source for diversion. DEA is unaware of the diversion of prescription drug products containing List I chemicals to clandestine drug laboratories.

With respect to controls, prescription drugs are already subject to stringent requirements governing their distribution and dispensing. A prescription drug can only be dispensed to the public pursuant to the order of a licensed health care professional. Further, distributors of prescription drug products are subject to extensive licensing, security, recordkeeping and inventory requirements. These requirements, the guidelines for which are set forth in 21 CFR, Part 205, establish a ''closed system'' for the distribution of prescription products.

In light of the existing controls and the lack of evidence of diversion of regulated prescription products, application of the registration requirement is unnecessary at this time for the enforcement of the CSA. In addition, the information maintained in the distribution records required under the FDA guidelines is sufficient to satisfy DEA's needs, should an inspection of the records be necessary. Therefore, DEA is proposing to amend 21 CFR Part 1309 to add a new Section 1309.28, waiving the requirement of registration for any person who distributes a regulated prescription drug product. Further, DEA is proposing to amend Section 1310.06 of the regulations, which currently allows that prescription and hospital records maintained in the course of medical practice are adequate for satisfying DEA's requirements, to also allow that records required to be maintained pursuant to the guidelines set forth in 21 CFR, Part 205 shall be adequate for wholesale distributions of regulated prescription drug products. If, however, evidence of diversion of prescription products is seen in the future, DEA will take action to make the products subject to the specific regulatory requirements of the CSA.

In addition to the proposed changes described above, Sections 1309.21 and 1309.22 are proposed to be amended to make reference to the addition of the new waiver of the registration requirement.

Under the CSA, the Attorney General may waive the requirement of registration for certain manufacturers, distributors or dispensers if it is consistent with the public interest (21 U.S.C. 822(d). The Attorney General has delegated authority under the CSA and all subsequent amendments to the CSA to the Administrator of the DEA (28 CFR 0.100). The Administrator, in turn, has delegated this authority to the Deputy Administrator pursuant to 28 CFR 0.104 (59 FR 23637 (May 6, 1994)).

The Deputy Administrator of the Drug Enforcement Administration hereby certifies that this proposed rulemaking will not have a significant impact on a large number of entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. This rulemaking proposes to grant those persons who distribute regulated prescription drug products relief from DEA's chemical registration requirement and allow for the use of records already maintained pursuant to FDA guidelines in lieu of requiring that separate records be maintained. These proposed amendments could potentially ease the regulatory burden for 1,200 or more distributors and manufacturers of regulated prescription drug products.

This proposed rule has been drafted and reviewed in accordance with Executive Order 12866. DEA has determined that this is not a significant regulatory action under the provisions of Executive Order 12866, section 3(f) and accordingly this rule has not been reviewed by the Office of Management and Budget. This rule will eliminate unnecessary regulatory requirements for distributors of regulated prescription drug products.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

21 CFR Part 1310

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

For reasons set out above, it is proposed that 21 CFR part 1309 be amended as follows:

PART 1309—[AMENDED]

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

2. Section 1309.21 is proposed to be revised to read as follows:

§ 1309.21 Persons required to register.

(a) Every person who distributes, imports, or exports any List I chemical, other than those List I chemicals contained in a product exempted under § 1310.01(f)(1)(iv), or who proposes to engage in the distribution, importation, or exportation of any List I chemical, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1301.24 through 1309.28. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(b) Every person who distributes or exports a List I chemical they have manufactured, other than a List I chemical contained in a product exempted under § 1310.01(f)(1)(iv), or proposes to distribute or export a List I chemical they have manufactured, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24 through 1309.28.

3. Section 1309.22 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1309.22 Separate registration for independent activities.

(a) * * *

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, unless otherwise exempted by the Act or §§ 1309.24 through 1309.28, except that a person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.

4. Section 1309.28 is proposed to be added to read as follows:

§ 1309.28 Exemption of distributors of regulated prescription drug products.

(a) The requirement of registration is waived for any person who distributes a prescription drug product containing a List I chemical that is regulated pursuant to § 1310.01(f)(1)(iv).

(b) If any person exempted by this section also engages in the distribution, importation or exportation of a List I chemical, other than as described in paragraph (a), the person shall obtain a registration for such activities, as required by § 1309.21 of this part.

(c) The Administrator may, upon finding that continuation of the waiver granted in paragraph (a) of this section would not be in the public interest, suspend or revoke a person's waiver pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and 1309.51 through 1309.57 of this part.

PART 1310—[AMENDED]

5. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

6. Section 1310.06 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1310.06 Content of records and reports.

* * * * *

(b) For purposes of this section, normal business records shall be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person. For prescription drug products, prescription and hospital records kept in the normal course of medical treatment shall be considered adequate for satisfying the requirements of paragraph (a) with respect to dispensing to patients, and records required to be maintained pursuant to the Federal Food and Drug Administration guidelines relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, shall be considered adequate for satisfying the requirements of paragraph (a) with respect to distributions.

* * * * *

Dated: September 11, 1995.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

FR Doc. 95–23774 Filed 9–25–95; 8:45 am]

BILLING CODE 4410–09–M

21 CFR Part 1310

[DEA–135P/RIN 1117–AA30]

Manufacturer Reporting

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to implement provisions of the Domestic Chemical Diversion Control Act of 1993 (Public Law 103–200) (DCDCA) to specify certain reporting requirements for manufacturers of listed chemicals. In a proposed rule published in the Federal Register on October 13, 1994 (59 FR 51887), the DEA previously proposed regulations to implement the requirement that bulk manufacturers of listed chemicals report certain data to the DEA. After receiving comments from the affected chemical industry, on December 9, 1994 (59 FR 63738) the DEA withdrew the portions of the proposed rule pertaining to manufacturer reporting requirements, for further study and consultation with industry. The proposed manufacturer reporting requirements as specified in this Notice of Proposed Rulemaking have been prepared with additional input from the affected chemical industry.

DATES: Written comments and objections must be received by November 27, 1995.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, Washington DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Howard McClain Jr., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: The Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200) (DCDCA) was signed into law on December 17, 1993 and became effective on April 16, 1994. A final rule implementing most of the provisions of the DCDCA (60 FR 32447) was published on June 22, 1995.

The DCDCA amended 21 U.S.C. 830(b) to require that regulated persons who manufacture a listed chemical (other than a drug product that is exempted under 21 U.S.C. 802(39)(A)(iv) report annually to DEA information detailing the specific quantities manufactured. The purpose of this provision is to provide DEA with information on the amounts of listed chemicals available in the U.S. and to enable the DEA to provide the International Narcotics Control Board (INCB) with aggregate data regarding the production and availability of chemicals controlled under provisions of the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

In a proposed rule published in the Federal Register on October 13, 1994 (59 FR 51887), the DEA proposed regulations to implement the provisions of the DCDCA. That notice proposed to amend Section 1310.03 to require that bulk manufacturers of listed chemicals report certain data to the DEA. In addition, Sections 1310.05 and 1310.06 were proposed to be amended to set forth the specific requirements for the chemical manufacturer reports. Comments received from the affected industry expressed concerns that the proposed manufacturer reports as set forth in Sections 1310.05 and 1310.06 may duplicate existing reports made by chemical manufacturers, did not take into consideration the treatment of confidential business information and were unduly burdensome. Therefore, on December 9, 1994, the DEA published a notice in the Federal Register (59 FR 63738) to withdraw the proposed provisions for manufacturer reporting (as set forth in 1310.05 and 1310.06) for reassessment and consultation with industry. Subsequent to the withdrawal, the DEA has solicited further input and advice from representatives of the affected chemical industry. Following